

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following documents:

D1: WO 97/13553 A (MEDTRAC TECH INC) 17 April 1997 (1997-04-17)

D2: US-A-5 284 133 (BURNS JAMES S ET AL) 8 February 1994 (1994-02-08)

1. Claim 1 does not meet the requirements of Article 6 PCT in that **the matter** for which protection is sought **is not clearly defined**. The claim attempts to define the subject-matter in terms of the result to be achieved (*...a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body...*), which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.
2. Furthermore, the above-mentioned lack of clarity notwithstanding, **the subject-matter** of claim 1 **is not new** in the sense of Article 33(2) PCT, and therefore the criteria of Article 33(1) PCT are not met.

Document D1 discloses a compliance monitor suitable for a drug delivery device for administering a drug, comprising:

a switch (1555) actuable by a user on delivering a dose from the device;
a sensor (435) for detecting whether the device is properly positioned relative to the user's body (if the user's inhalation is detected, then implicitly the device is properly positioned in the user's mouth) for delivery of the dose; and
a processor (605) coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated (page 33, line 15 - page 34, line 29).

2. Dependent claims 2-18 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (claims 1-4, 6-9 and 13-18) or inventive step (claims 5 and 10-12), see documents D1 and D2 and the corresponding passages cited in the search report.

Re Item VII

Certain defects in the international application

1. The independent claim 1 is not drafted in the two-part form, as normally required by Rule 6.3(b) PCT.
2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).